Docket No.: A000259-03-BHJ
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
William S. Bess et al.

Application No.: 09/535,005 Confirmation No.: 1060

Filed: March 23, 2000 Art Unit: 1623

For: FAST DISSOLVING ORALLY CONSUMABLE FILMS CONTAINING AN ION EXCHANGE RESIN AS A TASTE MASKING AGENT

Examiner: E. Peselev

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 1.192, this brief is being timely filed within two months of the receipt of the Notice of Appeal on March 14, 2005, which is extended to May 16, 2005, the next business day to May 14. Should a fee be due, please charge deposit account 23-0455. This Appeal Brief is submitted in furtherance of said Notice of Appeal.

The fees required under § 1.191 are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 1.192 and M.P.E.P. § 1206:

I. Real Party In Interest
II Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

Warner-Lambert Company, LLC a subsidiary owned by Pfizer Inc.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 33 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 5-13, 20, 23, 24 and 30-32

2. Claims withdrawn from consideration but not canceled: 0

3. Claims pending: 1-4, 14-19, 21, 22, 25-29, and 33-48

4. Claims allowed: 0

5. Claims rejected: 1-4, 14-19, 21, 22, 25-29 and 33-48

C. Claims On Appeal

The claims on appeal are claims 1-4, 14-19, 21, 22, 25-29 and 33-48

IV. STATUS OF AMENDMENTS

Applicant did not file an Amendment After Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

An orally consumable solid film including at least one water soluble polymer, and an adsorption complex, the adsorption complex includes at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent; and wherein the ratio of the at least one pharmaceutically active agent to the at least one ion exchange resin is about 1:3 to about 3:1; and wherein said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(a) Claims 1-4, 14-19, 21, 22, 28, 29 and 33-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,596,298 in view of Eichman (U.S. Patent No. 5,980,882).

(b) Claims 1-4, 14-19, 21, 22, 25-29 and 33-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (U.S. Patent No. 5,980,882) in combination with Schiraldi et al (U.S. Patent No. 4,713,243). Although the last Office Action does not specifically recite Ozaki as a basis of the obviousness rejection, it is not clear whether the rejection relying on Ozaki was withdrawn. As such, for the purposes of thoroughness, Applicants list Ozaki as a basis of an obviousness rejection in combination with Eichman and will provide an analysis of this rejection in the Argument Section. Claims 1-4, 14-19, 21, 22, 25-29 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (U.S. Patent No. 5,980,882) in combination with Ozaki et al (U.S. Patent No. 5,411,945) or Schiraldi et al (U.S. Patent No. 4,713,243).

ARGUMENTS

(a) Attached Terminal Disclaimer overcomes the rejection based on judicially created doctrine of obviousness-type double patenting

The rejection of claims 1-4, 14-19, 21, 22, 28, 29 and 33-39 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-20 of US Patent 6,596,298 to Leung will be overcome by the acceptance of the attached terminal disclaimer. The filing of a terminal disclaimer is not to be construed as an admission, estoppel or acquiescence. See *Quad Environmental Technology v. Union Sanitary District*, 20 USPQ2d 1392 (Fed. Cir.1991) and *Ortho Pharmaceuticals Corp. v. Smith*, 22 USPQ2d 1119 (Fed.Cir.992).

(b) Eichman in view of Schiraldi in view of Ozaki do not render obvious Claims1-4, 14-19, 21, 22, 25-29 and 33-48

Claims 1-4, 7, 14-19, 21, 22, 25-29 and 33-39 were rejected under 35 USC 103(a) as being obvious over U.S. Patent 5,980,882 to Eichman in view of US Patent 5,411,945 to Ozaki, et al.(herein also referred to as "Ozaki") or US Patent to Schiraldi et al.(herein also referred to as "Schiraldi"). Eichman in view of Ozaki, et al. or Schiraldi et al. fail to render obvious the above claims.

The above claims relate to an orally consumable solid film that comprises at least one water soluble polymer, an adsorption complex that comprises at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent or method of making the orally consumable solid film. The film is adapted to adhere to and dissolve in the mouth of a consumer.

Eichman fails to suggest the present invention since, among other things, Eichman does not even remotely suggest that the complexes discussed therein could or should be used in orally-consumable solid films containing at least one water soluble resin. Eichman states that the composition can be in the form of a tablet, a capsule, a powder, a lotion, a cream, a suppository, a syrup, a suspension, a nasal spray, an inhaler or an eye drop(see column 5, lines 31-37 and column 13, lines 30-37). Although, Eichman mentions numerous possible forms in which the compositions could possibly be used, Eichman is completely silent concerning films and films are not even remotely suggested in the disclosure by Eichman.

The statement in the office action that the drug-resin complex coated with a film as disclosed by Eichman is "an orally consumable film" is in error. Eichman refers to using ethyl cellulose, a **water insoluble** material, as the coating. Accordingly, the coated particles of Eichman are not films that dissolve in the mouth.

Furthermore, Eichman refers to coating finely divided powder or granules and not to forming films. In addition, the coated finely divided powder or granules of Eichman are not films adapted to adhere to and dissolve in the mouth of a consumer as recited in the present claims.

There is no reason of record (1) why it would be advantageous to modify Eichman to make a film, nor is there any reason of record why the skilled artisan would (2) utilize a water soluble polymer in the proportions necessary to create a solid rather than a gel or thickened suspension, let alone (3) produce a film from such material rather than the disclosed tablet and the like.

The conclusion in the office action that the product of Eichman would be expected to be less gritty because the product has improved dissolution characteristics is also in error. No relationship exists between dissolution properties and grittiness. Something can be readily dissolvable and feel very gritty, while a non soluble material might be quite soft and smooth. Also, the dissolution characteristics desired by Eichman relate to employing a diffusion barrier

which would prolong the dissolution of the drug-resin complex. It is not at all apparent why this would have any relevance to reduced grittiness.

(b) Ozaki was relied upon for a disclosure of the film-forming ability of pullulan. However, Ozaki fails to suggest that films of pullulan could be used in conjunction with a complex of a pharmaceutically active agent and an ion exchange resin to obtain an orally-consumable solid film. In fact, Ozaki even fails to suggest a film containing a pharmaceutically active agent. Instead, Ozaki suggests using films for wrapping an "unswallowable powdery medicine" that is similar to a medicinal wafer (see column 8, lines 11-26). This configuration is quite different from an orally consumable film that is adapted to adhere to and dissolve in the mouth of a consumer as recited in the present claims. Moreover, it was surprising that the ion-exchange resin could even be employed with and not be incompatible with the water soluble polymer. This was surprising in view of the differences solubility characteristics between the water soluble polymer and the ion exchange resin, which are disclosed as and known as not being water soluble.

Schiraldi does not overcome the above discussed deficiencies of Eichman and Ozaki with respect to rendering obvious the present claims. Schiraldi was merely relied upon for a disclosure of a pharmaceutical film containing a pharmaceutical agent and hydroxypropylcellulose adhering to a wet mucous surface. However, Schiraldi fails to suggest that films therein could be used in conjunction with a complex of a pharmaceutically active agent and an ion exchange resin to obtain an orally-consumable solid film. The structures of Schiraldi are intended to adhere to and remain in place over an extended period of time to provide controlled release of a pharmaceutical agent at the location wherein the film is placed. This is in contrast to the fast dissolving films of the present invention.

The cited art lacks the motivation for forming an orally consumable solid film of a water soluble resin and complex of a pharmaceutically active agent and an ion exchange resin. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention needed to sustain a rejection under 35 USC 103.

The mere fact that cited art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the cited art suggest the desirability of the modification. No such suggestion appears in the cited art in this matter. The Examiner's attention in kindly directed to *In re Lee* 61 USPQ2d 1430 (Fed. Cir.2002), *In re Dembiczak et al.* 50 USPQ2d. 1614 (Fed. Cir.1999), *In re Gordon*, 221 USPQ 1125 (Fed. Cir.1984), *In re Laskowski*, 10 USPQ2d. 1397 (Fed. Cir. 1989) and *In re Fritch*, 23, USPQ2d. 1780 (Fed. Cir.1992).

In *Dembiczak et al.*, supra, the Court at 1617 stated: "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc., v. M3 Sys., Inc., 157 F.3d. 1340, 1352, 48 USPQ2d. 1225, 1232 (Fed. Cir. 1998) (describing 'teaching or suggestion motivation [to combine]' as in 'essential evidentiary component of an obviousness holding'), In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d. 1453, 1459 (Fed. Cir. 1998) ('the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them');...".

The combination and balance of different properties that would be desired from the type of product to which this invention is directed are quite difficult to achieve. For instance, along with masking the taste of the active agent, the limitations on the size or volume of the film place demands on being able to achieve sufficient dosage of the active agent. This is to be accomplished without the need for unduly increasing the volume or dimensions of the film so as not to lose the advantage of its convenience. As discussed above, it was surprising that the ion-exchange resin could even be employed with and not be incompatible with the water soluble polymer. This was surprising in view of the differences solubility characteristics between the water soluble polymer and the ion exchange resin, which are disclosed as and known as not being water soluble.

Furthermore, it was not predictable that the presence of the ion exchange resin would be beneficial without adversely affecting the properties of the film such as damaging its integrity, or causing brittleness, grittiness or another undesirable feel, or dehydrating the film to an undesired

extent. In fact, attempts at coating the active agent and using the coated component in a film of a water soluble polymer, e.g. pullulan, resulted in a gritty and bitter product.

Along these lines, please see the comparative films in examples 1, 2 and 3 (Tables 1, 2 and 3) on pages 22-27 of the specification. On the other hand, films employing complexes of pharmaceutically active agents and ion exchange resins in accordance with the above claims exhibit desired appearance and taste characteristics. Please see examples 4-7 (Tables 4-7) on pages 27-32 of the specification.

The statement in the office action that the comparative examples are limited to the use of dextromethorphan as an active agent and the use of pullulan as a film forming agent and it cannot be predicted if additional agents encompassed by the instant claims will result in a film having desired property is misplaced. Nothing in the record suggests that the use of other materials encompassed by the instant claims would result in vastly different characteristics. Also, the claims are at least implicitly limited by common sense, if nothing else, to those combinations that form orally consumable films that are adapted to adhere to and dissolve in the mouth of a consumer. Furthermore, the comparative films shown are deemed to be a comparison to the closest prior art and to require more places an unjustified and undue burden and expense on the applicant. This is especially so in the present situation since a case of *prima facie* obviousness has not even been established. In fact the above statement in the office action runs counter to the case law such as *In re Goffe*, 191 USPQ 429, 431 (CCPA, 1976). While discussing a different rejection, but nonetheless relevant to the present situation, the Court made the following precautionary statement:

> " For all practical purposes the Board would limit appellants to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute . However to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet guidelines specified for 'preferred materials' in a process such as the

one herein involved would not serve the constitutional purpose of promoting progress in the useful arts".

Also, the cited art lacks the necessary direction or incentive to those of ordinary skill in the art to render the rejection under 35 USC 103 sustainable. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention, as discussed above, needed to sustain a rejection under 35 USC 103. See *Diversitech Corp. v. Century Steps, Inc.* 7 USPQ2d 1315 (Fed. Cir.1988), *In re Mercier*, 185 USPQ 774 (CCPA 1975) and *In re Naylor*, 152 USPQ 106 (CCPA 1966).

Moreover, the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d. 1923 (Fed.Cir. 1990), *In re Antonie*, 195, USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

No property can be ignored in determining patentability and comparing the claimed invention to the cited art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

The rejection of the claims is in the nature of "ought to be tried" which is an impermissible standard under 35 U.S.C. 103. See *Jones v. Hardy*, 220 USPQ 1021 (Fed.Cir., 1984).

Accordingly, the cited art fails to render obvious the above claims.

VI. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A do include the amendments filed by Applicant on November 29, 2004.

Application No.: 09/535,005 Docket No.: A0000259-03-BHJ

VII. EVIDENCE

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

VIII. RELATED PROCEEDINGS

No related proceedings are referenced in II. above, or copies of decisions in related proceedings are not provided, hence no Appendix is included.

Dated: 5/16/05

Respectfully submitted,

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/535,005

1. An orally consumable solid film comprising:

at least one water soluble polymer, and

an adsorption complex, said adsorption complex comprising at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent; and

wherein the ratio of the at least one pharmaceutically active agent to the at least one ion exchange resin is about 1:3 to about 3:1; and wherein said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

2. The consumable solid film according to claim 1, wherein said water soluble polymer is selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, amylose, high amylose starch, hydroxypropylated high amylose starch, dextrin, pectin, chitin, chitosan, levan, elsinan, collagen, gelatin, zein, gluten, soy protein isolate, whey protein isolate, casein and mixtures thereof.

3. The consumable solid film according to claim 2, wherein said water soluble polymer is pullulan.

4. The consumable solid film according to claim 1, wherein said pharmaceutically active agent is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory agents, antitussives, decongestants, anti-histamines, expectorants, anti-diaherrals, H_2-antagonists, proton pump inhibitors, central nervous system agents, analgesics and mixtures thereof.

5-13 (Cancelled)

14. The consumable solid film according to claim 1 wherein the pharmaceutically active agent provides from about 40 wt% to about 60 wt% of said adsorption complex.

15. The consumable solid film according to claim 14, wherein the ion exchange resin is a sulfonated polymer comprising polystyrene cross-linked with divinylbenzene.

16. The consumable solid film according to claim 14, wherein the ion exchange resin is a sulfonated polymer comprising polystyrene cross-linked with 8% of divinylbenzene, with an ion exchange capacity of about 4.5 to 5.5 meq/g of dry resin (H^+-form).

17. The consumable solid film according to claim 16, wherein the ion exchange resin comprises irregularly-shaped particles ranging in size from about 47 to about 149 micrometers.

18. The consumable solid film according to claim 16, wherein the ion exchange resin comprises spherical particles ranging in size from about 45 to about 150 micrometers.

19. The consumable solid film according to claim 14, wherein the ion exchange resin comprises polystyrene cross-linked with 8% of divinylbenzene functionalized with a quaternary ammonium group, said ion exchange resin having an exchange capacity normally within a range of about 3 to about 4 meq/g of dry ion exchange resin.

20. (Cancelled).

21. The consumable solid film according to claim 14, wherein said water soluble polymer is pullulan, said pharmaceutically active agent is dextromethorphan, and said taste masking agent is a sulfonated polymer ion exchange resin comprising polystyrene cross-linked with divinylbenzene.

22. The consumable solid film according to claim 21, comprising pullulan in an amount of about 40 to about 80 wt% of said film, dextromethorphan in an amount of about 5 to about 40 wt% of said film, and sulfonated polymer ion exchange resin in an amount of about 5 to about 40 wt% of said film.

23-24 (Cancelled)

25. A method for preparing the consumable solid film of claim 1, said method comprising:

dissolving the water-soluble polymer in water to provide an aqueous solution;

mixing water soluble film former and stabilizing agent to provide a solid-film forming mixture;

combining said solid-film forming mixture and said aqueous solution to provide a hydrated polymer gel;

mixing oils to form an oil mixture;

admixing said oil mixture and said hydrated polymer gel to provide a uniform gel, said uniform gel comprising said pharmaceutically active agent and said at least one ion exchange resin;

casting the uniform gel on a substrate; and

drying the cast gel to provide said solid film.

26. The method of claim 25, wherein said aqueous solution comprises both said pharmaceutically active agent and said at least one ion exchange resin.

27. The method of claim 25, wherein said pharmaceutically active agent is sorbed to said ion exchange resin without separating ion exchanged pharmaceutically active agent from unexchanged agent and counter ion salts.

28. An orally consumable solid film comprising a water soluble polymer, a pharmaceutically active agent and an ion exchange resin taste masking agent, wherein said ion exchange resin is present at a weight ratio to said pharmaceutically active agent of about 2:1 to about 1:2 and said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

29. The consumable solid film according to claim 28, wherein the ratio of ion exchange resin to pharmaceutically active agent is about 1:1.

30-32 (Cancelled).

33. The consumable film according to claim 22, wherein pullulan is present in said solid film in an amount of about 2 to about 6 mg/cm^2, dextromethorphan is present in said solid film in an amount of about 1.4 to about 2 mg/cm^2, and sulfonated polymer ion exchange resin is present in said solid film in an amount of about 1.4 to about 2 mg/cm^2.

34. The consumable solid film according to claims 22 or 33, further comprising:

about 0.01 to about 5 w% of at least one stabilizing agent;
about 0.001 to about 0.1 wt% of at least one of at least one coloring agent;
about 0.01 to about 70 wt% water;
about 0.1 to about 15 wt% of at least one sweetening agent;
about 0.1 to about 15 w% of at least one flavoring agent;
about 0.1 to about 4 wt% of at least one cooling agent;
about 0.1 to about 5 wt% of at least one surfactant;
about 0.1 to about 12 wt% of a triglyceride;
about 0.001 to about 5 wt% of a preservative;
about 0.01 to about 5 wt% of a polyethylene oxide compound; and
about 1 to about 20 wt% of propylene glycol.

35. The consumable solid film according to claim 1 wherein the pharmaceutically active agent comprises dextromethorphan or salt thereof or both.

36. The consumable solid film according to claim 1 wherein the pharmaceutically-active agent comprises phenylepherine or salt thereof or both.

37. The consumable solid film according to claim 2 wherein said water soluble polymer comprises polyvinyl alcohol.

38. The consumable solid film according to claim 2 wherein said water soluble polymer comprises hydroxypropyl cellulose.

39. The consumable solid film according to claim 1 wherein the pharmaceutically active agent comprises diphenhydramine or salt thereof or both.

40. The consumable solid film according to claim 2, wherein said pharmaceutically active agent is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory agents, antitussives, decongestants, anti-histamines, expectorants, anti-diaherrals, H_2-antagonists, proton pump inhibitors, central nervous system agents, analgesics and mixtures thereof.

41. The consumable solid film according to claim 1, wherein said film has a thickness of 0.009 ± 0.002 in.

42. The consumable solid film according to claim 1, wherein said film contains about 0.1% to about 10 wt% moisture.

43. The consumable solid film according to claim 1, wherein said film contains about 3% to about 8 wt% moisture.

44. The consumable solid film according to claim 1, wherein said film contains about 4% to about 7 wt% moisture.

45. An orally consumable solid film comprising:

at least one water soluble polymer selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, and hydroxypropyl cellulose, and mixtures thereof; and

an adsorption complex, said adsorption complex comprising at least one pharmaceutically active agent and at least one ion exchange resin as a taste masking agent; wherein said pharmaceutically active agent is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory agents, antitussives, decongestants, anti-histamines, expectorants, anti-diaherrals, H_2-antagonists, proton pump inhibitors, central nervous system agents, analgesics and mixtures thereof:

and

wherein the ratio of the at least one pharmaceutically active agent to the at least one ion exchange resin is about 1:3 to about 3:1; and wherein said orally consumable film is adapted to adhere to and dissolve in a mouth of a consumer.

46. The consumable solid film according to claim 45 wherein the pharmaceutically active agent comprises dextromethorphan or salt thereof or both.

47. The consumable solid film according to claim 45 wherein the pharmaceutically-active agent comprises phenylepherine or salt thereof or both.

48. The consumable solid film according to claim 45 wherein the pharmaceutically active agent comprises diphenhydramine or salt thereof or both.